EXHIBIT I

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October 12, 2018

VIA E-MAIL

Special Master David Cohen
U.S. District Court for the Northern District of Ohio
Carl B. Stokes U.S. Courthouse
801 West Superior Avenue
Cleveland, OH 44113

Re: In Re National Prescription Opiate Litigation
U.S. District Court for the Northern District of Ohio - Case No. 1:17-md-2804

Dear Special Master Cohen:

I write on behalf of defendant Rite Aid of Maryland, Inc. d/b/a Mid-Atlantic Customer Support Center ("Rite Aid of Maryland") in response to Mr. Pifko's October 8 letter seeking a ruling compelling production of "dispensing" information ("Pifko Letter"). Plaintiffs' application is meritless and should be denied.

Documents Concerning "Dispensing Practices, Policies And Procedures"

Mr. Pifko fails to identify in his letter any specific discovery requests by Plaintiffs to Rite Aid of Maryland to which he seeks to compel additional production or responses. This omission alone warrants denial of Mr. Pifko's application. Plaintiffs are required to identify the specific discovery request(s) to which they seek to compel additional responses and the allegedly inadequate answer(s) in order to provide notice of what is at issue and to enable a meaningful, specific response. *See* N.D. Ohio Local Rule 37.2. Plaintiffs have served numerous discovery requests on Rite Aid of Maryland, which incorporate forms of the word "dispense" or "dispensing,"[1] making it impossible to know from Mr. Pifko's vague and general letter exactly which discovery requests are at issue.

To the extent that Mr. Pifko seeks dispensing information directly related to suspicious order monitoring – such as a due diligence report in connection with a request to increase a distribution

[1] A copy of Plaintiffs' First Set of Requests For Production of Documents with each occurrence of the word "dispense" or "dispensing" highlighted is attached as Exhibit A hereto.

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threshold for a particular pharmacy that included a review of dispensing information – Rite Aid of Maryland has been producing and will continue to produce these documents.

To the extent, however, that Mr. Pifko seeks broader discovery of dispensing data, the request is baseless and should be rejected. The Rite Aid *distribution center* Plaintiffs elected to bring claims against does not own or operate retail pharmacies. Plaintiffs' myriad requests related to "dispensing" – such as joint ventures related to "dispensing," marketing materials related to "dispensing," and DEA registrations to "dispense"[2] – have nothing to do with Rite Aid of Maryland's distribution activities. Plaintiffs did not assert claims against Rite Aid of Ohio, Inc., which operates Rite Aid retail pharmacies in Ohio.

Moreover, in the briefing of the Motions to Dismiss, Plaintiffs **expressly disclaimed** pursuing claims against Rite Aid of Maryland or the other chain pharmacy defendants for pharmacy or dispensing practices. Plaintiffs represented to the Court that they "do not allege violations of statutes or regulations applicable specifically to retailers who sell opioids," but instead base their claims against the chain pharmacy defendants on "the requirements under the CSA and Ohio law applicable to distributors." Pls. Omnibus Mem. In Opp. To Mots. To Dismiss (ECF No. 654), at 75 n. 47. To permit Plaintiffs now to fundamentally change the nature of their case at this stage of the proceedings would impose enormous additional burdens on Rite Aid of Maryland. Considerations of fairness and proportionality weigh heavily against such an expansion of discovery.

While Plaintiffs assert that the information they seek is "highly relevant to Defendants' liability as distributors" (Pifko Letter at 1), it is revealing that in the last sentence of their letter they demand "that Defendants be required to produce responsive documents concerning 'dispensing,' **regardless of whether it is specifically tied to their role as distributors**." *Id.* at 4 (emphasis added). Such sweeping discovery is inappropriate, particularly considering the heavy demands and time constraints of this litigation.

Mr. Pifko asserts that dispensing information is "highly relevant to Defendants' liability as distributors" because of the "know your customer" due diligence requirements. *Id.* at 1. As support, Mr. Pifko cites an AmerisourceBergen ("ABDC") PowerPoint presentation containing observations concerning various forms of drug diversion. *Id.* at 3. Yet Mr. Pifko inexplicably fails to address another ABDC PowerPoint presentation that is much more relevant and that directly refutes the position he advances here. That ABDC PowerPoint presentation was made at a DEA conference and notes that "Retail chain pharmacies are exempted" from the "know your customer" due diligence requirements. ABDCMDL0000107. It was Mr. Pifko who established through his own questioning of ABDC 30(b)(6) witness Christopher Zimmerman on this PowerPoint that chain pharmacies were exempted from "know your customer" due diligence based on the DEA's input and approval:

> Q. This page provides some additional discussion of the Form 590 you were just talking about and the "know your customer" due diligence. Do you see that?
> A. Yes.
> Q. It says, Retail chain pharmacies are exempted. Do you see that?

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[2] *See, e.g.,* Plaintiffs' First Set of Requests For Production of Documents, Request Nos. 7, 10, and 16.

> A. Yes.
> Q. What does that mean?
> MR. NICHOLAS: Object to the form. If you know.
> THE WITNESS: So part of our negotiations with DEA, as we were developing this new, enhanced program, was who would this apply to. And they exempted retail chain pharmacies, I believe it was, over ten. There was a number that constituted chain. And that was during the negotiation process with DEA.
> BY MR. PIFKO:
> Q. And so the DEA told AmerisourceBergen that they could exempt them from this process?
> A. Yes.
> …
>
> Q. Did you have an understanding as to why retail chain pharmacies, as you said, of ten or more, were exempted from this requirement?
> A. Because at the time, the issue was a lot was around Internet pharmacies. And part of the 590 form, in addition to the pharmacists in charge, they also wanted ownership information. So a lot of the due
> diligence was around who owned the pharmacy. And it was a process. They figure chains are a corporate entity, they're all owned by -- so a lot of the information really didn't apply. And that was a lot of the discussion of why the chains were exempted.
>
> Christopher Zimmer Dep. Aug. 3, 2018, at 213:10-214:4, 216:13-217:5.

To this very day, the DEA website's description of the conference and that ABDC presentation includes a reference to the exemption of retail chain pharmacies from "know your customer" due diligence: "Mr. Zimmerman stressed the importance of knowing your customer, and providing due diligence investigations on all new retail and wholesale accounts, with the exception of retail chain pharmacies." *See* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html.

Documents Pursuant to Paragraph 9(k)(ii) of CMO No. 1

Plaintiffs are incorrect in asserting that a settlement entered by Rite Aid in 2009 is responsive to CMO No. 1 Paragraph 9(k)(ii). That section of the CMO requires production of non-privileged documents previously produced pursuant to a previous investigation, litigation or administrative action "involving the marketing or distribution of opioids." On its face, CMO No. 1 does not require production of documents concerning investigations or actions concerning "alleged violations of **dispensing** laws and regulations" which Plaintiffs ask you to order to be produced. In fact, Plaintiffs unsuccessfully sought to include obligations on Defendants related to dispensing information in CMO No. 1. *See* Plaintiff's Proposed Draft CMO #1, ¶ 22(k) (seeking to require each defendant to disclose information "identifying the total number of, and revenue from, prescriptions for Opioids that were **dispensed** in the United States since 1999") (emphasis added). Plaintiffs thus seek in the present application to relitigate an issue they previously raised and lost six months ago.

As we have previously explained to Mr. Pifko, and as is evident from the press release referenced by Mr. Pifko in his letter, the 2009 settlement concerned practices at individual Rite Aid retail

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pharmacies, not distribution by Rite Aid's *distribution center* in Maryland. Moreover, the settlement did not concern any Rite Aid pharmacies located in Ohio but rather concerned other jurisdictions where Rite Aid had pharmacy operations. It is therefore plainly not responsive to CMO No. 1 or otherwise relevant to the Track 1 cases.

Plaintiffs have been aware for several months that Rite Aid of Maryland maintains that the 2009 settlement is not responsive to CMO No. 1. Plaintiffs' request is untimely as well as meritless, and should be denied.

Respectfully,

John P. Lavelle, Jr.

JPL/dms
Attachment

cc: Defendants' Counsel (via email - xALLDEFENDANTS-MDL2804-Service@arnoldporter.com)
Plaintiffs' Counsel (via email - MDL2804discovery@motleyrice.com)

EXHIBIT A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *All Cases*	MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster

PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO RITE AID CORPORATION

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure as well as the Case Management Order in In re National Prescription Opiate Litigation (Dkt. No. 232 in No.:17-cv- 2804), Plaintiffs hereby request that Rite Aid Corporation (herein "Rite Aid") respond to the following Requests for Production (the "Requests") in accordance with its obligations under the Federal Rules of Civil Procedure. Responses to the Requests shall be provided in the manner required by Rule 34(b)(2), the Local Rules of the Northern District of Ohio, the Court's Case Management Order One, filed April 11, 2018, Doc. No. 232, and any other applicable law or rules, within thirty (30) days of the service of these Requests.

If Defendant finds any term or other aspect of the Requests vague, ambiguous or otherwise objectionable and intends to so object, counsel for the Plaintiffs offers to promptly meet with counsel for Defendant to resolve any issues.

DEFINITIONS

"You" or "Your," means Defendant Rite Aid and its officers, directors, employees, partners, representatives, agents, corporate parent, subsidiaries, affiliates, divisions,

predecessors or successors-in-interest, and other Persons or entities acting on its behalf or controlled by it.

"Document" is defined to be synonymous in meaning and equal in scope to the meaning of this term in Fed. R. Civ. P. 34. A draft or non-identical copy is a separate Document within the meaning of this term. In all events, the definition of "Document" shall include "Communication," as defined below.

"Communication" means the transmittal of information (in the form of facts, ideas, inquiries, or otherwise) and, with respect to oral Communication, includes any Document evidencing such oral Communication. It includes the transmittal of information by any means, including email, SMS, MMS or other "text" messages, messages on "social networking" sites (including but not limited to, Facebook, Google+, MySpace, and Twitter), shared applications from cell phones, or by any other means. "Communication" also shall include, without limitation, all originals and copies that are provided by you or to you by others.

"Customer" means any entity from which You secure revenue related to Your distribution and/or dispensing of Opioids or Opioid Products, or from the provision of services and/or solutions including:

a. manufacturers, suppliers, distributors and/or wholesalers of Opioids or Opioid Products, regardless of geographic location;

b. retail, national and regional pharmaceutical accounts, independent retail pharmacies, institutional healthcare providers, physicians, group purchasing organizations, healthcare providers and payors, pharmacies, internet pharmacies, integrated delivery networks, long-

term care providers, mail order pharmacies, mass merchandisers, hospitals and specialty practices located in either Cuyahoga or Summit counties in Ohio;

c. all payors that provide reimbursement or costs or charges arising out of the sale, provision and/or prescription of Opioids or Opioid Products, regardless of geographic location.

"Person" is defined as any natural Person or any business, legal, or governmental entity, or association.

"Opioid" or "Opioids" refers to that class of drugs, legal or illegal, natural or synthetic, used to control pain, including, but not limited to, the drugs referenced in Plaintiffs' Complaints and Amended Complaints in the above-referenced matter.

"Opioid Product" or "Opioid Products" refers to the Opioids that You distributed and/or dispensed. This includes coatings, capsule configurations, delivery systems or mechanisms that include, but are not limited to, anti-abuse, tamper resistant and crush-proof mechanisms and mechanisms to deter immediate release. Opioid Products is also intended to include rescue medication for break through pain.

"Suspicious Order" shall be as defined by the DEA and shall include, but not be limited to, orders for Opioids or Opioid Products of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency and/or by any policy, procedure or criteria established by You.

"Controlled Substances" shall be defined by the Controlled Substances Act.

"Quotas" mean aggregate, manufacturing, and procurement quotas established pursuant to 21 U.S.C. § 826 in accordance with 21 CFR 1303.11 and/or any other governmental entity.

INSTRUCTIONS

The time period covered by these requests is January 1, 1990 through the date of Your response, unless otherwise specified.

All ESI shall be produced in its original native form, including all metadata, and as otherwise provided in the to-be-agreed/ordered ESI protocol.

All video and audio files must be produced in the manner in which you store and retrieve them, *i.e.*, in their native formats and as otherwise provided in the to-be-agreed/ordered ESI protocol.

REQUEST FOR PRODUCTION

Corporate Structure and Relationships, Business Model and Financial Information

Request No. 1. All agreements to purchase, procure, distribute and/or dispense Opioids or Opioid Products between You and any of the Defendants in this matter, and/or any manufacturer, supplier, wholesaler, distributor, group purchasing organization or other entity in the supply chain not a Defendant to this action, including Documents sufficient to show Your compensation under those agreements.

RESPONSE:

Request No. 2. All agreements with any Customers to whom You distribute Opioid Products or provide services, including but not limited to, supply chain services, supply

chain management, supply chain safety, pharmacy services, provider and patient engagement programs, clinical trial support, patient assistance programs, reimbursement services, analytics, marketing, branding, advertising, inventory management, data reporting, new product launch and chargeback administration, pharmacy management services, pharmacy benefit management solutions, medication therapy management and patient outcomes services. Documents should be sufficient to show Your compensation under said agreements.

RESPONSE:

Request No. 3. All Documents regarding the safety or efficacy of Opioids or Opioid Products, including but not limited to all Documents evidencing any actions You took to evaluate, analyze, study or ensure that the Opioid Products You distributed were safe and effective and/or were safe and effective for chronic pain and long-term use.

RESPONSE:

Request No. 4. Documents sufficient to show the following on a monthly and yearly basis:

a. costs incurred and projections for each Opioid Product You have distributed;
b. cash flow for each Opioid Product You have distributed;
c. profit and/or loss for each Opioid Product you have distributed;
d. total revenue of all sales for each retail location in Cuyahoga and Summit Counties;

e. total revenue of all sales of Controlled Substances for each retail location in Cuyahoga and Summit Counties; and

f. total revenue of all sales of Opioid Products for each retail location in Cuyahoga and Summit Counties.

RESPONSE:

Request No. 5. All committee, departmental and/or Board of Directors meeting minutes, agendas, handouts, and attendance logs, including all draft versions of the same, relating to the marketing, sale, distribution, dispensing, safety, efficacy, reimbursement, or diversion of Opioids or Opioid Products.

RESPONSE:

Request No. 6. Your marketing plans, business plans, or strategic plans both nationally and by state and region relating to Opioids or Opioid Products, including any sales incentive policies.

RESPONSE:

Request No. 7. Documents sufficient to show the relationship between You and any joint venture, collaboration, co-marketing initiative, teaming agreement, or other similar

agreements created in whole or in part to undertake distribution and/or dispensing of Opioids or Opioid Products between You and any other Defendants in this matter.

RESPONSE:

Request No. 8. All Documents concerning training and compensation of Your agents, employees, or contractors, including but not limited to (a) training manuals outlining the identification and reporting of evidence concerning abuse, suspicious orders, or potential criminal activity and any measures You take regarding prevention of diversion, abuse or misuse of Opioid Products; (b) management training manuals instructing managers or trainers on how to provide such training; and/or (c) job descriptions for each marketing or sales and pharmacist and pharmacy technician position related to Your Opioid Products, including any officer(s) and vice presidents in charge of sales and dispensing.

RESPONSE:

Request No. 9. All Documents regarding the role of Your sales or marketing departments or any other departments with respect to Suspicious Orders from 1990 to present, including but not limited to (a) whether Persons responsible for overseeing, monitoring or reporting Suspicious Orders report, directly or indirectly, to Persons in the sales or marketing departments; and (b) the role or authority of Your sales or marketing departments in the hiring, firing, promotion, compensation, demotion, admonition,

discipline, commendation, or periodic performance reviews of Persons responsible for overseeing, monitoring or reporting Suspicious Orders.

RESPONSE:

Request No. 10. All marketing materials and/or other Documents from 1990 to the present provided to Customers relating to the distribution and/or dispensing of Opioids or Opioid Products and/or the provision of services including, but not limited to, supply chain services, supply chain management, supply chain safety, pharmacy services, provider and patient engagement programs, clinical trial support, patient assistance programs, reimbursement services, analytics, marketing, branding, advertising, inventory management, data reporting, new product launch and chargeback administration, pharmacy management services, medication therapy management and patient outcomes services.

RESPONSE:

Request No. 11. All Documents provided to any Customer regarding Opioids or Opioid Products whether created by You, received by You, or used or distributed by You, from 1990 to present, regarding the safety, efficacy or risk of Opioids or Opioid Products or prevention of diversion, abuse or misuse of Opioids or Opioid Products. This should include but not be limited to education and educational materials provided by industry

organizations, including Healthcare Distribution Alliance or Healthcare Distribution Management Association or distributed to You at any DEA conference, seminar, summit, or meeting.

RESPONSE:

Request No. 12. All Documents regarding Your agreements with, membership in, attendance, participation, or involvement in any meeting, council, committee, task force, or working group of any industry trade group or association about the manufacture, development, formulation, marketing, advertising, sale, dispensing, reimbursement, pricing, distribution, Quotas or diversion of Opioids or Opioid Products or laws, rules or regulations or proposed laws, rules or regulations applying to Opioids or Opioid Products, including but not limited to:

a. Healthcare Distribution Management Association (HDMA);

b. Healthcare Distribution Alliance (HDA);

c. Pain Care Forum (PCF);

d. National Association of Chain Drug Stores (NACDS);

e. National Association of Drug Diversion Investigators (NADDI);

f. National Council for Prescription Drug Program (NCPDP);

g. National Community Pharmacists Association (NCPA);

h. National Association of Wholesalers (NAW);

i. National Community Pharmacists Association (NCPA); and

j. Pharmaceutical Research and Manufacturers of America (PhRMA).

RESPONSE:

Quotas and Supply

Request No. 13. All Documents regarding the assessment and establishment of thresholds, needs, Quotas, or rescheduling[1] for Opioids or Opioid Products. This should include, but not be limited to, Documents sent or received between You and any governmental entity, Customer, pharmacy/dispenser You own and/or control, third party, manufacturer of Opioids or Opioid Products, distributor of Opioid or Opioid Products, lobbyist or lobbying entity and any trade association or member or employee thereof, as well as data and analyses prepared in connection with proposed Quotas, such as projected demand estimates, net disposal information, inventories and production cycles.

RESPONSE:

Request No. 14. All Documents related to any thresholds or Controlled Substance limits for each Customer of Your Opioid Products from January 1, 1990 to the present or Communications between You and said entity regarding thresholds or limits on orders of Controlled Substances, including but not limited to, all Documents, data or analytics generated from or used in Your Controlled Substances Threshold Management Program or any similar program, committee, or data analytics system.

[1] This is specifically intended to include all Documents regarding the rescheduling of hydrocodone combination products from a Schedule III to a Schedule II drug in 2014, and any actions related to said rescheduling dating back to 1996.

RESPONSE:

Request No. 15. All Documents analyzing, examining or describing the effect that a reduction or failure to increase any Quota, threshold or Controlled Substance Limits for Opioids or an Opioid Product would have on Your business, profits, sales or financial outcome for any year between 1990 and the present.

RESPONSE:

Interactions with the DEA and Other Government Entities

Request No. 16. All Documents related to Your DEA registration to distribute and/or dispense Controlled Substances from January 1, 1990 to the present, including all Form DEA-224, Form DEA-224A, DEA-225 and Form DEA-225A applications submitted by You regarding any of Your distribution centers and/or pharmacies that sold prescription Opioids or Opioid Products from January 1, 1990 to the present, and all Documents regarding any government actions affecting or potentially affecting Your DEA registration to dispense and/or distribute.

RESPONSE:

Request No. 17. All Documents related to Your Ohio Board of Pharmacy registration to distribute and/or dispense Controlled Substances from January 1, 1990 to the present, including all applications, renewal applications, and attestations submitted by You regarding any of Your distribution centers that sold or distributed prescription Opioids or Opioid Products from January 1, 1990 to the present, and all Documents regarding any government actions affecting or potentially affecting Your Ohio Board of Pharmacy registration to dispense and/or distribute.

RESPONSE:

Request No. 18. All Documents related to or that You sent to or received from any governmental entity, including but not limited to the United States Congress, Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), United States Department of Justice (DOJ), United States Patent Office, United States Government Accountability Office f/k/a General Accounting Office or any state attorney general or Board of Pharmacy regarding (a) Opioids or Opioid Products; and/or (b) any government investigation, inquiry, administrative action or criminal proceeding involving Opioids or an Opioid Product and/or other Schedule II or Schedule III drugs, from 1990 to the present. Your response should include:

a. All Documents related to Suspicious Orders of Controlled Substances and any Suspicious Order monitoring programs;

b. All Documents related to the Settlement and/or other actions outlined in Interrogatory No. 26;

c. All Documents related to "guidance letters" and/or "Dear Registrant" letters sent to You by the DEA related to the distribution of Controlled Substances, the reporting of Suspicious Orders or Suspicious Order monitoring programs;

d. All Documents related to the DEA's Distributor Initiative Program, including but not limited to briefings provided by the Diversion Control Division;

e. All Documents related to any DEA briefings, Letters of Admonition (LOA), Orders to Show Cause (OTSC), Immediate Suspension Orders (ISO), Memoranda of Understanding (MOU), Notices of Inspection (NOI) and/or Administrative Inspection Warrants (AIW);

f. All Documents related to any state Board of Pharmacy notice of violation or potential violation.

RESPONSE:

Request No. 19. All Documents of or concerning Communications with any legislative or administrative body, including efforts to lobby government officials or entities with respect to laws, regulations or administrative actions or determinations concerning Opioids or Opioid Products, as well as all Documents and Communications with third parties You employed, worked with or collaborated with respect to those interactions with any legislative or administrative body or government official(s), including but not limited to Documents concerning lobbying or advocacy related to Opioids or Opioid Products (including Documents evidencing the money spent by You on lobbying or advocacy), statements of work or agreements with those third parties, and any work product You received from those third parties. Your response should include but is certainly not limited to any such information regarding:

a. All Documents related to Communications with Rep. Tom Marino [R-PA] regarding distribution and/or dispensing of Controlled Substances.

b. All Documents related to the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 enacted by the 114th United States Congress and signed into law by President Barack Obama on April 19, 2016.

c. All Documents regarding Your response to the Subcommittee on Oversight and Investigations of the United States House of Representatives Energy and Commerce Committee arising out of the *Letters to Distributors and the DEA Regarding Alleged Pill Dumping in West Virginia* dated May 9, 2017.

RESPONSE:

Request No. 20. Transcripts of testimony, as well as any video-taped testimony by any of Your current or former employees, officers or directors, or agents, in any court case, mediation, government investigation, government hearing or arbitration regarding the dispensing and/or distribution of Opioids or any Opioid Products, including any exhibits referred to in that testimony.

RESPONSE:

Data, Internal Controls and Compliance

Request No. 21. All Documents, data, electronic data interchange (EDI) and databases You received, generated, had access to or maintained from 1990 to present regarding sales or distribution or channel data monitoring of Opioids or Opioid Products, including those received, generated or available from any Customer. This includes, but is not limited to any EDI 810 (Invoice Transaction), EDI 820 (Payment Order/Remittance

Advice), EDI 832 (Sales Catalog), 844 (Product Transfer Account Adjustment/Chargeback submission), EDI 849 (chargeback reconciliation), EDI 845 (Contract notification), EDI 850 (purchase order), EDI 852 (Inventory and Sales), EDI 855 (Purchase Order Acknowledgement), EDI 856 (Advanced Ship Notice), EDI 867 (Detailed Sales reconciliation). This request includes, but is not limited to such information from IMS Health, QuintilesIMS, Iqvia, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, ValueCentric, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors") and all agreements between You and any Data Vendor, Customer, or third party providing such data, including any fee-for-service and/or inventory management agreements. This should include any analysis of that data and all Documents sufficient to show all Persons who had knowledge of, created, received or participated in that analysis and sufficient to show Your ownership interest in any Data Vendor. This should also include, but is not limited to, all analysis of the supply or shipments into a particular geographic location in relation to the population size and past supply history, diversion or abuse.

RESPONSE:

Request No. 22. All Documents, reports, submission, data, or information that You were required to maintain, deliver, make, or submit for or to the DEA pursuant to 21 U.S.C. § 801 et seq. and 21 C.F.R. § 1301.01 et seq. as well as all drafts of those Documents

and internal communications discussing, describing, or relating to the Documents responsive to this request.

RESPONSE:

Request No. 23. All Documents regarding Your establishment and design of a system to detect, investigate and/or address any Suspicious Orders of Opioids or Opioid Products or detect, investigate and/or address signs of diversion, abuse or misuse of Opioids or Opioid Products.

RESPONSE:

Request No. 24. All Documents related to the basis for Your compensation of Persons responsible for addressing, overseeing, monitoring or reporting Suspicious Orders from 1990 to present, including Documents that evidence whether compensation is based, in whole or part, on levels of sales of Controlled Substances, revenue or profitability and all annual or periodic performance reviews or evaluations of all Persons responsible for overseeing, monitoring or reporting Suspicious Orders from 1990 to present, including all metrics or goals used for each review or evaluation, and all Documents regarding each review or evaluation, including any recommendation of adverse employment decisions due to the level of sales of Controlled Substances.

RESPONSE:

Request No. 25. All Documents related to Your procedures, policies, protocols, internal controls or instructions to identify, prevent, investigate, report and/or halt potential abuse, diversion, unlawful sales, distribution or transfer of Opioids or Opioid Products, including but not limited to any procedures, policies, protocol, internal controls or instructions from 1990 to present regarding:

a. the detection and reporting of Suspicious Orders and/or to maintaining effective controls against diversion of Controlled Substances;

b. monitoring sales of Controlled Substances;

c. conducting an independent analysis of Suspicious Orders prior to completing a sale to determine whether the Controlled Substances are likely to be/being diverted from legitimate channels to illegitimate channels;

d. Your Suspicious Order monitoring system (SOMS) including any metrics, tools, models, workflows, platforms, computer program[s] and/or protocol[s] used or utilized in that program or system;

e. defining, discussing, referring or related to criteria used to determine Suspicious Orders such as set forth in 21 C.F.R. § 1301.74(b);

f. Customer due diligence to evaluate whether these entities are engaged in excessive and/or Suspicious Ordering and/or dispensing, including but not limited to, utilization reports, questionnaires, order histories, survey responses, and records of site visits;

g. threshold limits of Controlled Substances and/or the methodology used to establish thresholds and/or threshold limits; and

h. Standard Operating Procedures related to the monitoring, investigation, and reporting of Suspicious Orders.

This Request seeks but is not limited to all Documents related to Your procedures, policies, protocols, internal controls or instructions related to compliance with Your duty to:

a. "maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels," 21 U.S.C.A. § 823(b)(1);

b. "provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 CFR 1301.71(a);

c. "design and operate a system to disclose to the registrant Suspicious Orders of Controlled Substances," 21 CFR 1301.74(b);

d. "inform the Field Division Office of the Administration" of "Suspicious Orders when discovered by the registrant," 21 CFR 1301.74(b);

e. address "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," 21 CFR 1301.74(b);

f. address the shipment, fulfillment, prevention, or the halting of suspicious orders;

g. act with due diligence regarding the discovery of Suspicious Orders;

h. establish a "Know Your Customer" program;

i. conduct any due diligence performed for new Customers prior to filling orders of Opioids; and

j. fulfilling your duty under 21 CFR 1306.04(a) for proper dispensing of controlled substances

RESPONSE:

Request No. 26. All Documents generated by the policies, procedures, protocols and controls described in the immediately above Request from 1990 to present. This includes, but is not limited to, orders, order histories, pharmacy utilization reports, Customer

Communication, sales representative notes, Customer files, due diligence files, "Know Your Customer" questionnaires, survey responses, documentation of actual or proposed threshold limits and/or Controlled Substance limits, records of investigations, Communication with governmental entities, data and data analysis.

RESPONSE:

Request No. 27. All Documents concerning any audit, review, investigation or due diligence performed following any indication of Suspicious Orders received by You, including the date of the audit or investigation, the outcome, and any subsequent actions by You, including any restrictions in the supply of Opioid Products as a result of such an audit, review, investigation or due diligence. This request includes Documents received by You from Your employees, agents, Customers, or third parties about violations of Your policies and/or procedures which relate in any way to Suspicious Orders.

RESPONSE:

Request No. 28. All Documents relating to the ARCOS database or the data and information derived from the ARCOS database, including, but not limited to, all reports, analysis and/or summaries utilizing data contained in the ARCOS database; all statements, reviews, evaluations and/or comments regarding the value and/or utilization of

the ARCOS database; and all policies, procedures and internal controls or instructions regarding ARCOS database reporting.

RESPONSE:

Request No. 29. All Documents relating to the Ohio Automated Rx Reporting Systems (OARRS) database or the data and information derived from the OARRS database including but not limited to all reports, analysis and/or summaries utilizing data contained in the OARRS database and all statements, reviews, evaluations and/or comments regarding the value and/or utilization of the OARRS database.

RESPONSE:

Request No. 30. All Documents sufficient to show how You track and secure from receipt to delivery Your Opioid Products, Your interactions with Customers, regarding volume of deliveries or Suspicious Orders, including Documents sufficient to show how You deliver Opioid Products and any data You provide to any manufacturers regarding the distribution or delivery of Opioid Products or the volume of Opioid Products delivered to each Customer and/or pharmacy/dispenser that You own and/or control. This request includes historical changes or modifications.

RESPONSE:

Request No. 31. All Documents summarizing, documenting, or evidencing reimbursement to any Customer for Opioids or Opioid Products, including but not limited to, Rebate Management System (RMS) Letters, Customer or manufacturer reimbursement, rebates, spot reduction discounts, or "chargeback" programs and/or fee-for-service, inventory management or other agreements pertaining to any such reimbursements, rebates, chargebacks, or discounts. This request is intended to include any and all Documents or information that was provided to any Customer in exchange for "chargebacks" or any other type of rebate.

RESPONSE:

Request No. 32. All Documents relating to Your role, input or contribution, whether direct or indirect, monetary or otherwise, in any marketing, sales, educational or promotional program conducted or created by any of Your Customers relating to Opioid or Opioid Products.

RESPONSE:

Request No. 33. Please produce a transactional log for all distributions of prescription Opioids or Opioid Products for Summit County, Ohio; Cuyahoga County, Ohio; and the City of Cleveland, Ohio, separately, from January 1, 1990 to present. This transactional

log should include the following fields of information and be provided in a format that is readily searchable:

a. Reporter DEA Number
b. Reporter Business Activity Description
c. Reporter Name
d. Reporter Address
e. Reporter City
f. Reporter State
g. Reporter Zip
h. Reporter County
i. Buyer DEA Number
j. Buyer Business Activity Description
k. Buyer Name
l. Buyer Address
m. Buyer City
n. Buyer State (Ohio)
o. Buyer Zip Code
p. Buyer County
q. Transaction Code
r. Drug Code (oxycodone (9143), hydrocodone (9193), hydromorphone (9150), and fentanyl (9801))
s. NDC Number
t. Drug Name
u. Drug Quantity
v. Unit
w. Action Indicator
x. Order Form Number
y. Correction Number
z. Strength
aa. Transaction Date (mmddyyy)
bb. Calculated Base Weigh in Grams (Weight of Drug)
cc. Dosage Unit
dd. Transaction ID

RESPONSE:

Request No. 34. Produce all Documents related to any and all "Suspicious Orders" that were identified by You or any system You employed related to orders for Opioid or Opioid Products from January 1, 1990 to present for Summit and Cuyahoga Counties and the City of Cleveland. This request includes but is not limited to all Documents related to due diligence regarding each Suspicious Order, the results of the due diligence, any reporting that was done to the DEA or Ohio Board of Pharmacy related to the Suspicious Order, as well as any Documents that indicate whether the order was shipped or not.

RESPONSE:

Request No. 35. Please produce all Documents to and/or from the DEA related to You consenting or objecting to the disclosure of ARCOS data to a third-party arising out of a FOIA request or otherwise. This request includes but is not limited to all responses to notices provided under 28 C.F.R. §16.8(e) and Your detailed written statement that specifies all grounds for withholding the particular information. *See also Madel v. U.S. Dep't of Justice*, 784 F.3d 448 (8th Cir. 2015). This request also includes any and all Documents related to the DEA's release of ARCOS data to any party, including any compact with any governmental entity related to future release of ARCOS data.

RESPONSE:

Dated: June 5, 2018

s/Peter H. Weinberger

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 5th day of June 2018, the foregoing has been served via email only to the following defense liaison counsel:

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